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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,561	02/01/2001	Gec--Kee Sim	HKZ-029CPUS	2245

7590

06/17/2002

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EXAMINER

ROARK, JESSICA H

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/646,561	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Jessica H. Roark	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <u>copy of Pethon Decision</u> |

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### DETAILED ACTION

1. Applicant's Renewed Petition under 37 CFR 1.47(a), filed 9/17/01, is acknowledged. The Petition was GRANTED on 11/29/01. A copy of the DECISION is attached.

*Claims 1-39 are pending and being acted upon presently*

### *Sequence Compliance*

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

### *Restriction Requirement*

3. Prior to setting forth the restriction requirement, it is noted that numerous SEQ ID NOS and clones are present in the pending claims. The Examiner has determined from the specification as filed that these SEQ ID NOS and clones can be grouped into those related to canine B7-1, canine B7-2, canine CTLA4, feline B7-1, feline B7-2 and feline CTLA4 molecules.

In view of the complexity of the instant claims reciting what appears to be several inter-related SEQ ID NOS: and clone designations; the Groups have been set forth generally based upon the relationships noted above. There does not appear to be unity of invention for the reasons set forth below.

Upon election of a Group, *Applicant is required to identify which SEQ ID NOS and clone names read on the elected invention.* It is noted that the Group should include the relevant full length molecule, coding sequence of the full length, soluble forms of the molecule (both full length sequences and coding), complements of these molecules, and all relevant clone names. For example, if an election of "canine B7-1 nucleic acid molecules.." of Group I is made, it appears that Applicant would indicate that the relevant SEQ ID NOS are SEQ ID NOS:1, 3, 4, 5, 11, 13, 14, 15; and that the relevant clones are those designated either "nCaB7-1..." or "nCaB7-1s..."

*Given the complexity of the instant claims, failure to provide the above indicated information would be considered non-responsive to the restriction requirement.*

Any additional cooperation provided by Applicant to provide claims that clearly defined the elected invention would be greatly appreciated.

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4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

**Nucleic Acids:**

Group I, claims 1-3, 6, 8, 10-14, 16-20, 22-23, 25-26 and 37-38, drawn to *canine B7-1* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

Group II, claims 1-3, 6, 8, 10-14, 16-20, 21, 23, 25-26 and 37-38, drawn to *canine B7-2* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

Group III, claims 1-3, 6, 8, 10-13, 15-20, 22-26 and 37-38, drawn to *feline B7-1* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

Group IV, claims 1-3, 6, 8, 10-14, 16-20, 21, 23, 25-26 and 37-38, drawn to *feline B7-2* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

Group V, claims 1-2, 6, 8, 10-14, 16-19, 26 and 37-38, drawn to *canine CTLA4* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

Group VI, claims 1-2, 6, 8, 10-14, 16-19, 26 and 37-38, drawn to *feline CTLA4* nucleic acid molecules, compositions thereof, methods of producing the proteins encoded by the nucleic acid, as well as recombinant molecules, vectors and host cell comprising these nucleic acids.

**Proteins:**

Group VII, claims 4-6, 27-28, 30-31, 33 and 35-37, drawn to *canine B7-1* proteins and compositions and multimers thereof.

Group VIII, claims 4-6, 27-28, 30-32 and 35-37, drawn to *canine B7-2* proteins and compositions and multimers thereof.

Group IX, claims 4-6, 27-28, 30-31 and 33-37, drawn to *feline B7-1* proteins and compositions and multimers thereof.

Group X, claims 4-6, 27-28, 30-32 and 35-37, drawn to *feline B7-2* proteins and compositions and multimers thereof.

Group XI, claims 4-6, 27-28, 31 and 36-37, drawn to *canine CTLA4* proteins and compositions and multimers thereof.

Group XII, claims 4-6, 27-28, 31 and 36-37, drawn to *feline CTLA4* proteins and compositions and multimers thereof.

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**Antibodies:**

Group XIII, claims 6, 29 and 37, drawn to antibodies to *canine B7-1* proteins, and compositions thereof.

Group XIV, claims 6, 29 and 37, drawn to antibodies to *canine B7-2* proteins, and compositions thereof.

Group XV, claims 6, 29 and 37, drawn to antibodies to *feline B7-1* proteins, and compositions thereof.

Group XVI, claims 6, 29 and 37, drawn to antibodies to *feline B7-2* proteins, and compositions thereof.

Group XVII, claims 6, 29 and 37, drawn to antibodies to *canine CTLA4* proteins, and compositions thereof.

Group XVIII, claims 6, 29 and 37, drawn to antibodies to *feline CTLA4* proteins, and compositions thereof.

**Mimetopes:**

Group XIX, claims 6 and 37, drawn to mimetopes of *canine or feline B7-1* proteins, and compositions thereof.

Group XX, claims 6 and 37, drawn to mimetopes to *canine or feline B7-2* proteins, and compositions thereof.

Group XXI, claims 6 and 37, drawn to mimetopes to *canine or feline CTLA4* proteins, and compositions thereof.

**Methods of Regulating T cell Responses:**

Group XXII, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *canine B7-1 nucleic acid* or composition thereof.

Group XXIII, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *canine B7-2 nucleic acid* or composition thereof.

Group XXIV, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *feline B7-1 nucleic acid* or composition thereof.

Group XXV, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *feline B7-2 nucleic acid* or composition thereof.

Group XXVI, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *canine CTLA4 nucleic acid* or composition thereof.

Group XXVII, claims 7 and 37-39, drawn to a method of regulating a T cell mediated immune response comprising administering a *feline CTLA4 nucleic acid* or composition thereof.

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Group XXVIII, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *canine B7-1 proteins* and compositions and multimers thereof.

Group XXIX, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *canine B7-2 proteins* and compositions and multimers thereof.

Group XXX, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *feline B7-1 proteins* and compositions and multimers thereof.

Group XXXI, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *feline B7-2 proteins* and compositions and multimers thereof.

Group XXXII, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *canine CTLA4 proteins* and compositions and multimers thereof.

Group XXXIII, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *feline CTLA4 proteins* and compositions and multimers thereof.

Group XXXIV, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *canine B7-1* proteins or compositions thereof.

Group XXXV, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *canine B7-2* proteins or compositions thereof.

Group XXXVI, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *feline B7-1* proteins or compositions thereof.

Group XXXVII, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *feline B7-2* proteins or compositions thereof.

Group XXXVIII, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *canine CTLA4* proteins or compositions thereof.

Group XXXIX, claims 7, 37 and 39, drawn to a method of regulating a T cell mediated immune response comprising administering *antibodies* to *feline CTLA4* proteins or compositions thereof.

**Methods of Identifying:**

Group XL, claim 9, drawn to a method to identify a compound, comprising contacting a *canine B7-1* protein with a putative inhibitory compound.

Group XLI, claim 9, drawn to a method to identify a compound, comprising contacting a *canine B7-2* protein with a putative inhibitory compound.

Group XLII, claim 9, drawn to a method to identify a compound, comprising contacting a *feline B7-1* protein with a putative inhibitory compound.

Group XLIII, claim 9, drawn to a method to identify a compound, comprising contacting a *feline B7-2* protein with a putative inhibitory compound.

Group XLIV, claim 9, drawn to a method to identify a compound, comprising contacting a *canine CTLA4* protein with a putative inhibitory compound.

Group XLV, claim 9, drawn to a method to identify a compound, comprising contacting a *feline CTLA4* protein with a putative inhibitory compound.

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6. The inventions listed as Groups I-XLV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Invention of Group XXI was found to have no special technical feature that defined the contribution over the prior art of El Tayar et al. (US Pat. No. 6,337,316) (see entire document).

El Tayar et al. teach a peptidomimetic of human CTLA4 (e.g., see Abstract and SEQ ID NO:2) that is a cyclized peptide involving the "MYPPPY" sequence of CTLA4 known to be important for ligand binding (e.g. see column 2, especially lines 30-39).

Since the "MYPPPY" sequence is also present in the CTLA4 proteins of the instant invention, the peptidomimetic of El Tayar et al. would also be a mimetope of the instant CTLA4 proteins.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Patent Examiner  
Technology Center 1600  
June 13, 2002

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